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PATENT
P-4815-US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): CHAIN, Daniel G.

SERIAL NO.: 10/084,380 EXAMINER: P.DUFFY

FILED: February 28, 2002 GROUP ART UNIT: 1645

FOR.: ANTIBODIES WHICH ARE FREE END-SPECIFIC FOR THE N-TERMINUS OR THE C-TERMINUS OF AN AMYLOID B PEPTIDE, PHARMACEUTICAL COMPOSITIONS AND METHOD OF USE THEREOF

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes:

1. ☒ Documents including patents, publications, and other information listed on the attached Form PTO-1449 for consideration by the Examiner;
2. ☐ Form PTO-1449 which lists documents including patents, publications and other information for consideration by the Examiner but in accordance with 37 C.F.R. 1.98(d) does not include those documents which have been previously cited or submitted to the Patent Office in the following prior application U.S. Serial No. _____, filed _____ which is properly identified and relied on.
3. ☐ Other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application.

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search

has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

I) ☒ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or

II) ☐ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first;

1. ☐ The undersigned hereby states that each item of information listed on the Form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

2. ☐ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of $180.00 under 37 C.F.R §1.17 (p) to Deposit Account 05-0649.

III) ☐ After the period in (I) and (II) but before the payment of the issue fee,

1. The Undersigned hereby states:

a) ☐ that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

2. ☐ The Undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of $180.00 under 37 C.F.R §1.17 (p) to Deposit Account 05-0649.

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 05-0649.

Respectfully submitted,

Mark S. Cohen
Attorney for Applicant(s)
Registration No. 42,425

Dated: May 30, 2002

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 4

Complete if Known	
Application Number	**09/402,820**
Filing Date	**October 12, 1999**
First Named Inventor	**CHAIN, Daniel G.**
Group Art Unit	**1543**
Examiner Name	**P. Duffy**
Attorney Docket Number	**P-4815-US**

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	5,688,651		Beka Solomon	Nov 18, 1997	
	AB	6,114,113		Seubert et al	Sep 5, 2000	
	AC	5,441,870		Seubert et al.	Aug 15, 1995	
	AD	5,721,130		Seubert et al.	Feb 24, 1998	
	AE	5,231,000		Ron Majocha et al.	Jul 27, 1993	

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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	AF	WO	96/18900		WIPO	Jun 20, 1996		☐
	AG	WO	89/01975		WIPO	Mar 09, 1989		☐
	AH	EP	0 683 234		Europe	Nov 22, 1995		☐
	AI	WO	98/44955		WIPO	Oct 15, 1998		☐
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Examiner Signature		Date Considered	

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 Of 4

Complete if Known	
Application Numb r	09/402,820
Filing Date	October 12, 1999
First Named Inventor	CHAIN, Daniel G.
Group Art Unit	1543
Examiner Name	P. Duffy
Attorney Docket Number	P-4815-US

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	AJ	BUSCIGLIO J, ET AL, (1193) "Generation of b-amyloid in the secretory pathway in neuronal and nonneuronal cells" Proc. Natl. Acad. Sci. 90, 2092-2096	☐
	AK	GEGEDDES JW ET AL. (1999) "N-terminus truncated b-amyloid peptides and C-terminus truncated secreted forms of of anyloid precursor protein: distinct roles in the pathogenesis of Alzheimer's disease" Neuobiol of Aging 20, *75-79.*	☐
	AL	HAAS C ET AL. (1992) "Amyloid b-peptide is produced by cultured cells during normal metabolism" Nature 359, 322-325	☐
	AM	HAAS C ET AL. (1993)"Cellular processing of β amyloid precursor protein and the genesis of amyloid β-peptide." Cell 75, <1039-1042	☐
	AN	HIGGINS LS ET AL. (1996) "p3 b amyloid peptide has a unique and potentially pathogenic immunohistochemical profile in Alzheimer's disease brain." Am. J. Pathol 149, 585-596	☐
	AO	JOHNSON-WOOD K. ET AL. "Amyloid precursor protein processing and A beta42 deposition in a transfenic mouse model of Alzheimer disease" Proc Natl. Acad. Sci U.S.A. 1997 Feb 18;94 (4): 1550-5	☐
	AP	LALOWSKI M (1996) "The nonamyloidogenic p3 fragment (amyloid β 17-42) is a major constituent of Down's syndrome cerebeller preamyloid." J Biol Chem 271, 33623-31	☐
	AQ	LARNER AJ (1999) "Hypothesis: amyloid b peptides truncated at the N-terminus contribute to the pathogenesis of Alzheimer's disease." Neurbiol. Of Aging 20, 65-69.	☐
	AR	MASTERS CL ET AL. (1985) "Amyloid plaque core protein in Alzheimer's disease and Down syndrome." *Proc. Natl. Acad. Sci. 82, 4245-9*	☐
	AS	MILLER DL ET AL. (1994) "Peptide compositions of the cerebrovascular and senile plaque core amyloid deposits of Alzheimer's disease." Archives of Biochemistry and Biophysics 301, 41-52	☐
	AT	NASLUND ET AL. (1994) "Relative abundance of Alzheimer Aβ amyloid peptide variants in Alzheimer disease and normal aging." Proc. Natl. Acad. Sci. USA 91, 8378-8382	☐
	AU	PIKE CJ ET AL. (1995) "Amino-terminal deletions enhance aggregation of β-amyloid peptides in vitro." J Biol Chem 270, 23895-8	
	AV	SEUBERT ET AL. (1992) "Isolation and quantification of soluble Alzheimer's β-peptide from biological fluids." Nature 359, 325-327	
	AW	VIGO-PELFREY C ET AL. (1993) "Characterization of beta-amyloid peptide from human cerebrospinal fluid." J Neurochem 61, 1965-8	
	AX	HANAN, Eilat et al., "Inhibitory effect of monoclonal antibodies on Alzheimer's Beta-amyloid peptide aggregation" INT. J. EXP. CLIN. INVEST., vol 3, pp. 130-133 (1996).	
	AY	SOLOMON, Beka et al., "Monoclonal antibodies inhibit in vitro fibrillar aggregation of the Alzheimer Betaamyloid peptide", PROC. NATL. ACAD. SCI. USA, vol. 93, pp 452-455 (1996)	

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First Named Inventor	CHAIN, Daniel G.
Group Art Unit	1543
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	AZ	SOLOMON, Beka et al., "Disaggregation of Alzheimer Beta-amyloid by site-directed mAb.", PROC. NATL. ACAD. SCI. USA, vol. 94, pp 4109-4112 (1997)	
	BA	TSUZUKI et al., "amyloid beta protein in rot soleus muscle in chloroquine-induced myopathy using end-specific antibodies for A beta 40 and A beta 42: immunohistochemical evidence for amyloid beta protein", Neurosci Letters 202 (1-2):77-80 (1995)	
	BB	TURNER et al., "Mayloids β40 and β42 Are Generated Intracellularly in Cultured Human Neurons and Their Secretion Increases with maturation", J Biol Chem 271 (15):8966:8970 (1996)	
	BC	YANAGISAWA et al., "Fractionation of Amyloid β protein (Aβ) in Alzheimer's Disease and Down's Syndrome Brains: Presence of Membrane-Bound Aβ", Ann NY Acad Sci 786:184-194 (1996)	
	BD	GRAVINA et al., "Amyloid β Protein (Aβ) in Alzheimer's Disease Brain: Biochemical and Immunocytochemical Analysis with Antibodies Specific for Forms Ending at Aβ40 or Aβ42(43)", J boil Chem 270 (13): 7013-7016 (1995)	
	BE	HARRINGTON et al.,"Characterisation of an epitome specific to the neuron-specific isoform of human enolase recognized by a monoclonal antibody raised against a synthetic peptide corresponding to the C-terminus of β/A-protein", Biochim Biophys Acta 1158:120-127 (1993)	
	BF	HIGGINS et al., "Transgenic Mouse Brain Histophathology Resembles Early Alzheimer's Disease", Ann Neurol 35:598-607 (1994)	
	BG	IWATSUBO et al., "Visualization of Aβ42 (43) and Aβ40 in Senile Plaques with End-Specific Aβ Monoclonals: Evidence that an Initally Depsoited specids is Aβ42(43) Neuron 13:45-53 (1994)	
	BH	IWATSUBO et al., "Amyloid β protein (Aβ) Deposition: Aβ42 (43) Precedes Aβ40 in Down Syndrome". Ann Neurol 37:294-299 (1995)	
	BI	KONIG et al., "Development and Characterization of a Monoclonal Antibody 369. 2B Specific for the Carboxyl-Terminus of the βA4 Peptide", Ann NY Acad Sci 777:345-355 (1996)	
	BJ	MANN et al., "The extent of amyloid deposition in brain in patients with Down's Syndrome does not depend upon the apolipoprotein E genotype", Neurosci Letters 196 (1-2):105-108 (1995)	
	BK	MANN et al., "Predominant Deposition of Amyloid β42 (43) in Plaques in Cases of Alzheimer's Disease and Hereditary Cerebral Hemorrhage Associated with Mutations in the Amyloid Precursor Protein Gene", Am J Pathol 148 (4):1257-1265 (1996)	
	BL	MANN et al., "Amyloid beta protein (Abeta) deposition in chromosome 14-linked Alzheimer's diseas: predominance of Abeta 43 (43) Ann Neurol 40 (2):149-156 (1996)	
	BM	MURPHY et al., "Development of a Monoclonal Antibody Specific for the COOH-Terminal of β-Amyloid 1-42 and Its Immunohistochemical reactivity in Alzheimer's Disease and Related Disorders", Am J Pathol 144 (5):1082-1088 (1994)	
	BN	NAKAMURA et al., "Carboxyl end-specific monoclonal antibodies to amyloid beta protein (A beta) subtypes (A beta 40 and A beta 42 (43) differentiate A beta in senile plaques and amyloid angiopathy in brains of aged cynomolgus monkeys." Neurosci Letters 201(2):151-154 (1996)	

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First Named Inventor	CHAIN, Daniel G.
Group Art Unit	1543
Examiner Name	P. Duffy
Attorney Docket Number	P-4815-US

	BO	SAIDO et al., "Spatial Resolution of Fodrin Proteolysis in Postischemic Brain", J Biol Chem 268(33): 25239-25243 (1993)	
	BP	SUZUKI et al., "High Tissue Content of Soluble β1-40 is Linked to Cerebral Amyloid Angiopathy", Am J Pathol 145 (2):452-460 (1994)	
	BQ	TAMAOKA et al., "Amyloid β protein 1-42/43 (Aβ 1-42/43) in cerebellar diffuse plaques: enzyme-linked immunosorbent assay and immunocytochemical study", Brain Res 679:151-156 (1995)	
	BR	DUERIASE et al. Bio Techniques, 16 (3): 436-482	
	BS	JOHNSON-WOOD K. ET AL, "Amyloid precursor protein processing and A beta42 deposition in a transgenic mouse model of Alzheimer disease," 1997, Proc Natl Acad Sci U S A Feb 18;94(4), pp 1550-5.	

Examiner Signature		Date Considered	

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